

MAR 21 2002

K014197

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3. Summary of Safety and Effectiveness Information

<b>Sponsor</b>	Synthes (USA) 1690 Russell Road Paoli, PA 19301
<b>Company Contact</b>	Matthew M. Hull (610) 647-9700 ext. 7191
<b>Name of the Device</b>	Synthes High Tibial Osteotomy Plate
<b>Device Classification(s)</b>	Class II, §888.3030 – Plate, Fixation, Bone
<b>Substantial Equivalence</b>	Documentation was provided which demonstrated the Synthes High Tibial Osteotomy Plate to be substantially equivalent to another legally marketed device.
<b>Device Description</b>	The Synthes High Tibial Osteotomy Plate is a flat, triangle shaped metal plate, that works as a tension band utilizing traditional internal plate/screw fixation.
<b>Indications</b>	The Synthes High Tibial Osteotomy Plate is intended for closing wedge high tibial osteotomies for treatment of bone and joint deformities and misalignment caused by injury or disease such as osteoarthritis.
<b>Material</b>	Stainless Steel



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 21 2002

Matthew M. Hull, RAC  
Senior Regulatory Affairs Specialist  
Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301

Re: K014197

Trade/Device Name: Synthes High Tibial Osteotomy Plate  
Regulation Number: 21 CFR §888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HRS  
Dated: December 19, 2001  
Received: December 21, 2001

Dear Mr. Hull;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

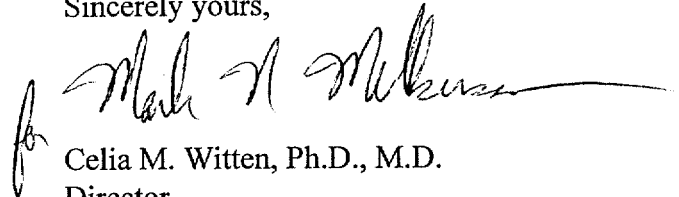
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Matthew Hull

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html> .

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2. **Indications for Use Statement**

510(k) Number (if known):

K014197

Device Name:

Synthes High Tibial Osteotomy Plate

Indications for Use:

The Synthes High Tibial Osteotomy Plate is intended for closing wedge high tibial osteotomies for treatment of bone and joint deformities and misalignment caused by injury or disease such as osteoarthritis.

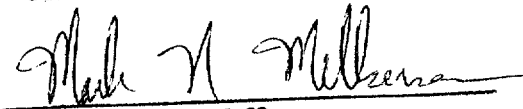
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   

for   
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K014197